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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 19/04 — A1

(11) International Publication Number: WO 92/13497

(43) International Publication Date: 20 August 1992 (20.08.92)

(21) International Application Number: PCT/GB92/00171

(22) International Filing Date: 29 January 1992 (29.01.92)

(30) Priority data:

9102070.1	31 January 1991 (31.01.91)	GB
9103320.9	16 February 1991 (16.02.91)	GB
9108263.6	17 April 1991 (17.04.91)	GB

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(81) Designated States: AT (European patent), AU, BE (European patent), CA, CH (European patent), DE (European patent), DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), GR (European patent), IT (European patent), JP, LU (European patent), MC (European patent), NL (European patent), NO, SE (European patent), US.

Published
With international search report.

(54) Title: RUBBER GLOVES, THEIR MANUFACTURE AND USE

(57) Abstract

A medical glove which may be donned by a dry or damp hand comprises a microtextured medical glove, provided on its inside surface with a surfactant and/or silicone. The microtextured glove is preferably a chlorinated medical glove which has been treated with polydimethyl siloxane hexyldecyl pyridinium or sodium lauryl sulphate, or a mixture of two of these materials.

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RUBBER GLOVES, THEIR MANUFACTURE AND USE

Background to the Invention

Medical personnel such as doctors, nurses, paramedics and the like and especially surgeons, frequently use natural rubber gloves to protect their patients and themselves from potential bacteriological or viral contamination. Gloves of this type will be referred to herein as "medical gloves" for the sake of convenience.

A long standing problem with medical gloves is that they can be difficult to don. In order to mitigate this difficulty it has been a long standing practice to powder the gloves so that the hand slips more easily into the glove. However, a number of medical authorities and a number of glove users are dissatisfied with the use of powder as a donning aid. This dissatisfaction stems from practical difficulties such as the occasional need to remove excess powder after donning and from concerns that some powders could lead to granulomas in some circumstances.

In order to provide medical gloves that could be easily donned without recourse to powder the art has provided two main and very different types of solution.

The first solution is to employ a natural rubber that has been treated with chlorine so that the medical glove is more easily donned. The alternative solution is to bond a layer of synthetic polymer to the inside (that is wearer contacting surface) of the medical glove and thereby render it more easily donned.

Examples of chlorinated medical gloves are given in US Patent No. 4304008 and examples of providing a layer of synthetic polymer on medical gloves are given in US Patents Nos. 3813695, 4482577, 4499154, 4548844, 4575476, 3856561, 3919442, 3967014, 4027060, 4082862, 3286011 and 3411982.

It can be difficult and expensive to provide medical gloves that employ a layer of synthetic polymer that is well bonded to the natural rubber and is sufficiently lubricious to dispense with the need for powders. The provision of such layers also tends to require the use of organic solvents with their associated hazards.

Chlorinated medical gloves can be manufactured without the use of organic solvents and have found widespread use. Unfortunately such gloves are only easily donned if the hands are dry and many users (in particular many surgeons) have damp hands at the point

where they will don the gloves (for example, a surgeon's hands will still be damp following having scrubbed with an antibacterial agent). This severely limits the use of chlorinated medical gloves.

It is an object of the present invention to provide a medical glove that avoids the need to employ an inside layer of synthetic polymer over the natural rubber but which is still readily donable by the dry or damp hand without the recourse to powders.

Summary of the Invention

The present invention provides a medical glove that is readily donable by the dry or damp hand without requiring an inside layer of synthetic polymer or a powder. The medical glove according to the present invention comprises a microtextured medical glove provided on the inside surface with one or both of a surfactant or a silicone. When used herein the term microtextured means that the glove surface has been roughened, for example by treatment with halogen or an acid (see for example "Surface Treatment of Rubber to Reduce Friction" by A D Roberts and C A Brackley in J Nat Rubb Res 4(1), 1-21).

Detailed Description of the Invention

The present invention provides a medical glove

which may be donned by the dry or damp hand which comprises a microtextured medical glove the inside surface of which is provided with one or both of a surfactant or a silicone.

The microtextured glove may be microtextured on the inside only or on both the inside and the outside.

The microtextured medical gloves for use in the invention may be obtained by treating the surface of a glove by halogenation, or an acid (especially an oxidising acid). Most suitably the microtextured medical glove is a halogenated medical glove. Preferably the microtextured medical glove is a chlorinated medical glove.

One of the advantages of employing chlorinated medical gloves is that they will be familiar to many users as a number of excellent commercial chlorinated gloves are already available such as Ansell's Powder Free, Sensotech G204 from LRC and Pristine from Fuji Latex and Perry Style 47 from Smith & Nephew Perry.

(These commercially available gloves have good dry hand donning properties but of course lack the desirable damp hand donning properties of the gloves of the present invention).

The gloves of the present invention are most suitably surgeons gloves.

From the foregoing it will be appreciated that in a preferred aspect the present invention provides a medical glove which may be donned by the dry or damp hand which comprises a chlorinated medical glove the inside surface of which is provided with one or both of a surfactant or a silicone.

The surfactant employed may be any suitable surfactant for use on the skin, that is a skin compatible surfactant. Such surfactants may be ionic or non-ionic. Mixtures of surfactants that is mixtures containing more than one surfactant, for example, two surfactants may be used if desired.

Suitable ionic surfactants include cationic, anionic and amphoteric (zwiterionic) surfactants.

Suitable cationic surfactants include alkyl, alkenyl, aralkyl and aryl group containing surfactants containing at least one liphophilic moiety (for example one of said group of for example 8 to 18 carbon atoms) and a salted nitrogen atom, for example such as a salted trialkylamine group, piperidinum group or the

like. Any counter ion present will be skin compatible such as a halide, for example chloride. Particularly suitable cationic surfactants include alkyl and alkenyl pyridinium compounds, for example those wherein the liphophilic moiety has from 12 to 18 carbon atoms. Preferred cationic surfactants include cetyl pyridinium chloride (also called hexadecyl pyridinium chloride).

Suitable anionic surfactants include alkyl, alkenyl, aralkyl and aryl group containing surfactants containing at least one liphophilic moiety (for example one of said group of for example 8 to 18 carbon atoms) and a salted acid group, for example a carboxylic, sulphonic, sulphuric, phosphoric, phosphonic or like acid group. Any counter ion present will be skin compatible, for example an alkali metal ion such as sodium or potassium of which sodium is preferred. Particularly suitable anionic surfactants include alkyl and alkenyl sulphates, for example those wherein the lipophilic moiety has from 12 to 18 carbon atoms. Preferred anionic surfactants include sodium lauryl sulphate.

Suitable amphoteric surfactants include those containing the above described cationic and anionic groups.

Suitable non-ionic surfactants include those containing residues of ethylene oxide, for example polyethoxylated fatty alcohols, polymers of ethylene oxide and copolymers of ethylene oxide and propylene oxide.

Suitable polyethoxylated fatty acids include those where an alkyl, alkelyl group of 8 to 18 carbon atoms or a sorbitan or similar group carry from 1 to 10, usually 2 to 8 polyoxyethylene residues wherein the polyoxyethylene residue has about 15 to 80 oxyethylene groups. Such materials are available commercially under trade marks such as **TWEEN, BRIJ, SPAN, GENEROL** and **TERGITOL, MYRJ, ANTAROX** and **TRITON. TWEEN** (polyoxyethylene sorbitan esters of fatty acids such as laurate, palmitate, sterate, oleate) and **ANTAROX** (nonylphenol ethoxylates) are of particular interest.

Suitable polymers of ethylene oxide and propylene oxide are generally block copolymers and are also commercially available, for example under such trade marks as **PLURONIC, TERGITOL, BRIJ** and **GENEROL.**

A class of surfactants which can be used which are ionic but also employ polyethylene oxide are those in which the ionic moieties are joined to the lipophilic moieties by polyoxyethylene moieties.

A preferred surfactant is a hexadecylpyridinium chloride. A preferred mixture of surfactants contains a hexadecylpyridinium chloride and sodium lauryl sulphate.

The silicone employed may be any polysiloxane or the like skin compatible silicone. Preferably the silicone is a liquid silicone. Apt silicones include polysiloxanes such as polydimethylsiloxane and analogous compounds in which some of the methyl residues are replaced by other functions such as the alkyl, aryl, aralkyl, alkenyl, alkoxy and the like. Alternatively the polysiloxane may be terminated by a non-siloxane moiety such as polyethyleneoxide dimethylsilyl, aminoethyldimethylsilyl, hydroxyethyldimethylsilyl, hydroxyethyldimethylsilyl or the like.

Preferably the polysiloxane employed is polydimethylsiloxane.

Although the surfactant and the silicone may be used separately, it is most apt to employ the surfactant and it is preferred to use them both.

From the foregoing it will be realised that in a

particularly preferred aspect this invention provides a surgeons glove that may be donned by the dry or damp hand which comprises a chlorinated surgeons glove the inner surface of which is provided with cetyl pyridinium chloride and sodium lauryl sulphate.

The amount of surfactant and/or silicone present on the inner surface of the glove may be any that is sufficient to aid damp hand donning but is typically very low, for example it is not necessary to leave a readily visible deposit on the surface (although if it is desired to leave a readily visible amount this may be done).

Aptly the amount of surfactant and/or silicone on the surface is that which can be deposited from an aqueous system solution and/or emulsion containing at least 0.1% w/w of surfactant and/or at least 0.05% w/w of a silicone. The aqueous system would not generally contain more than about 10% w/w of surfactant and/or more 2.5% by weight of a silicone, at a non-extreme temperature (for example 5 - 50°C, more usually 10 - 35°C, favourably 15 - 30°C, for example at 20°C) for a period of at least 1 minute. Generally the deposition takes place over a period of not more than 30 minutes, for example 5 to 20 minutes. An example of a suitable aqueous system contains about 0.1 to 10% w/w of

surfactant and 0.01 to 2.5% w/w of siloxane.

A particularly appropriate method of applying the surfactant and/or silicone is given in the examples hereto.

Most aptly a surfactant and/or a silicone is applied to both surfaces of the medical glove.

The gloves of this invention may be manufactured by treating their inside surface with a surfactant and/or silicone. The treatment may also coat the outside surface of the glove if desired.

Normally the surfactant and/or silicone will be used in aqueous solution and/or emulsion.

The concentrations, temperatures and times may be as hereinbefore mentioned.

A suitable method for treating the inside and/or outside of the microtextured glove at the same time is to tumble the microtextured glove in the coating liquid and then to dry the glove, for example in a tumble dryer.

The treatment with surfactant and/or silicone can

be carried out on a glove immediately after microtexturing or later. Thus, for example, a glove can be chlorinated in conventional manner in a chlorine bath, optionally rinsed, and then immersed in a bath of surfactant and/or silicone and thereafter dried.

Microtexturing may be introduced by physical or chemical means. A suitable physical means is to mould the rubber surface, for example by depositing the rubber latex onto a former which is pattened. Suitable chemical means include etching, treatment with a halogenating agent an acid or the like.

The microtexturing cannot be seen with the eye as individual raised or depressed areas. However in some cases a haziness can be seen. The spacing between adjacent raised areas will aptly be less than 100 microns, most aptly will be less than to microns and preferably will be less than 30 microns. The spacing between adjacent raised areas will aptly be greater than 0.5 microns, most aptly will be greater than 1 micron and preferably will be greater than 1.5 microns.

A particularly favoured method of producing a microtextured surface where the spacing between adjacent raised areas is 1 to 10 microns and most aptly 2 to 6 microns is treatment with a chlorinating agent.

A particularly favoured method of producing a microtextured surface where the spacing between adjacent raised area is to 1 to 10 microns and most aptly 2 to 6 microns is treatment with a chlorinating agent.

A particularly favoured method of producing a microtextured surface where the spacing between adjacent raised areas is 10 to 100 microns, most aptly 15 to 50 microns and favourably 20 to 30 microns is to form the rubber on a former processing the mirror image of the desired microtexture.

The inner surface of the glove may employ two types of microtexturing, for example (i) that produced by physical means such as moulding and also (ii) that produced by chemical means such as treatment with a halogenating agent, for example chlorination. It is preferred to employ two types of microtexturing since the wet donning performance of the glove is generally better than if only one type of microtexturing is employed.

The glove may also have a macrotexturing on its inner surface. Such macrotexturing is often readily visible to the eye. The spacing between raised areas

will aptly be more than 100 microns, more aptly more than 200 microns, most aptly more than 450 microns, for example about 500 to 1000 microns. A spacing of about 800 microns has been found to be particularly suitable. Macrotexturing may be produced by physical means such as by forming on a former which is provided with the mirror image of the macrotexturing sought.

The depth of the macrotexturing ("average peak to tough height") will generally be about 1 to about 100 microns. Aptly the depth of the macrotexturing will be greater than 2 microns, more aptly greater than 4 microns, most aptly greater than 10 microns. Aptly the depth of the macrotexturing will be less than 70 microns, more aptly less than 50 microns and most aptly less than 35 microns. A preferred depth of macrotexturing is about 20 to 30 microns, for example about 25 microns.

It is preferred to employ macrotexturing and microtexturing since the wet donning performance is particularly enhanced in such circumstances.
The glove formers required to give texturing of the type referred to herein are well known in the art because hitherto such formers have been employed to provide a roughened outer surface to the glove. In the present invention what is traditionally the outer

surface of the glove becomes the inner surface in use (that is the glove is inverted and the normally outside surface is next to the skin). The formers can be made by sand blasting porcelain formers, spattering formers with glaze or just by using appropriate unglazed porcelain formers. The use of unglazed porcelain formers (which has the typical feel of unglazed porcelain) have lead to particularly suitable gloves of this inventions when chlorinated and treated with surfactant on the donning (inner) surface.

US Patents Nos. 4597108, 4851266, 3992221, 3740262 and 3637411 and European Patent Application No. 88119875 may be read for methods of halogenating gloves.

Gloves may be chlorinated by immersion in a chlorination bath. This can be done in a manner which chlorinates both surfaces or the hand contacting surface only. If both surfaces are to be chlorinated gloves can be maintained open in the bath. If only the hand contacting surface is required to be chlorinated the glove can be on a former and thereafter inverted or can have its opening closed or be maintained flat and thereafter inverted.

The gloves can be maintained in the chlorination

bath for any convenient time, for example from about 15 seconds to 2 hours, but are more usually in the chlorination bath for from about one minute to one hour, more aptly more than one minute, most aptly more than 5 minutes and preferably more than 8 minutes, and more aptly for less than 20 minutes, most aptly less than 15 minutes and preferably less than 12 minutes.

Chlorination may be effected in any convenient manner but one particularly apt method is by dipping in a bath of water containing one part by weight of concentrated hydrochloric acid and 6 parts by weight of sodium hypochlorite solution (5% available Cl). The gloves may be immersed in the chlorination bath for a range of times, for example 1, 5, 10 20 and 30 minutes. The sides that form the outsides of the gloves in the chlorine bath formed the insides (as worn) of the gloves. After chlorination the gloves may be dried in an oven at 70°C for 30 minutes or at any other convenient temperature and time.

The insides (as worn) of the gloves may be treated with a surfactant and silicone mixture in water. The mixture may consist (by weight) of 2% cetylpyridinium chloride (CPC) and 0.5% DC 365. The gloves may be treated by holding them open and then filing them with the surfactant/silicone mixture and

then emptying them again. The gloves can be then dried at 70°C for 30 minutes or at any other convenient temperature and time.

The gloves produced in such a manner may be donned using damp hands.

The wet donning performances of such gloves in the absence of CPC/silicone treatment, seem to show an optimum at between 5 and 10 minutes chlorination. The use of the CPC/silicone treatment improves the performance of such gloves; the optimum chlorination time seeming to lie between 10 and 30 minutes.

SEM study has revealed changes in latex texture according to dwell time in the chlorine bath. A fine texture, similar to that of a cauliflower floret was seen throughout. Between 1 and 10 minutes chlorination one can see that furrows are being gradually etched into the latex, leading to a crazed appearance; while the non-furrowed areas tend to retain their cauliflower floret appearance.

Slippery latex surfaces are desirable on the inside (as worn) of gloves as they aid donning. However, on the outside of gloves an excessively slippery surface is undesirable as it may make the

holding of instruments difficult. As increasing the degree of chlorination makes surfaces more slippery differential chlorination between the inside and outside surfaces (as worn) can be advantageous.

Gloves may be made on unglazed porcelain formers.

The gloves may then be chlorinated by allowing the side that formed the inside (as worn) be the outside of a glove as placed into a chlorine bath between 1 and 30, for example for 10 minutes. The gloves may then be removed, drained and inverted before being placed back into the chlorine bath for a further 1 minute when both surfaces were chlorinated. After chlorination the gloves may be dried at 70°C for 30 minutes or any convenient temperature and time.

The gloves may then have CPC/silicone applied to the inside (as worn) surface only by filling the glove with the solution of the two agents.

The most advantageous gloves of this invention are sterile surgeon's gloves. Such gloves are most aptly distributed in bacteria-proof packaging to maintain sterility. Most aptly the packaging is of paper or plastic film. Favourably the packaging is in the form of a peel-apart container such as a pouch.

Thus in a highly preferred aspect the present invention provides a surgeon's glove of the invention as hereinbefore described which is a sterile glove within a backeria-proof peel-apart pouch.

The sterile glove of this invention may be sterilised in convenient manner, for example by treatment with ethylene oxide or ionizing radiation such as gamma irradiation. Methods of sterilizing gloves are very well known in the art.

The following examples illustrate the invention.

Example 1

Size 7.5 "Ansell No Powder" gloves (chlorinated on both surfaces) were placed in a bath having the following composition.

	ml		
Distilled water	960.5		
Hexadecylpyridium chloride	20	=	2%
Dow Corning 365 Medical Grade Silicone Emulsion (35%)	19.5	=	0.5%

The gloves were left for 15 minutes at room

temperature. They were then dried at 70°C for 30 minutes, being reversed after 15 minutes to totally dry the inside. When dry they were reversed again back to their original orientation.

Example 2

Example 1 was repeated omitting the hexadecylpyridinium chloride.

Example 3

Example 1 was repeated omitting the silicone.

Example 4

Example 1 was repeated coating the inner surface only.

Example 5

The glove of Example 1 was placed in a pouch with a peel-apart closure and the pouch closed. The glove and pouch were sterilized by treatment with ethylene oxide in conventional manner.

Example 6

(a) Preparation of Basic Glove

A glove was formed on an unglazed porcelain former in conventional manner by dipping the former into a calcium ion coagulant and then into a wax free natural rubber latex, drying, leaching in water and curing. The glove was powdered on the outside with starch to prevent adhesion until after chlorination.

(b) Chlorination

A glove prepared as described in (a) was placed in a chlorine bath which comprises a solution in water (465g) of concentrated hydrochloric acid (5g) and sodium hypochlorite solution (30g, 5%). The glove was tumbled in the bath for 10 minutes at room temperature (approximately 20°C). The glove was removed from the solution and washed with water and thereafter dried at 70°C for 30 minutes. About two thirds through the drying procedure the glove was inverted to ensure both surfaces were dry. The glove was inverted again so that the roughened side was on the outside.

(c) Slip Treatment

The glove then was immersed in a bath containing

water (100g) in which was cetylpyridinium chloride (2g) and a silicone, Dow Corning 365 (35%, 1.42g) so that both sides were treated.

The treated glove was dried at 70°C for 30 minutes being inverted about mid way through to ensure both surfaces were dry. At the end of this process the roughened and slip treated side is on the inside as worn.

Example 7

A glove made as in Example 6(a) was tumbled in a chlorine bath as described in Example 6(b) for ten minutes. The glove was replaced in the bath and tumbled for a further one minute. The glove was removed, washed with water and thereafter dried at 70°C for 30 minutes. About two thirds through the drying procedure the glove was inverted to ensure both surfaces were dry. With the roughened side on the inside the inside only was treated with a solution as described in Example 6(c). The solution was emptied from the glove and the glove dried at 70°C for thirty minutes inverting twice during the procedure to dry thoroughly and to place thr roughened side on the inside of the glove.

Example 8

Size 7.5 Perry Style 47 gloves (chlorinated on both surfaces) marketed by Smith & Nephew Perry, were sprayed on the inside surface with a solution having the following composition:

Distilled water	960ml		
Hexadecylpryidinium chloride	20g	=	2%
Sodium Lauryl Sulfate	20g	=	2%

The gloves were dried for 30 minutes. When dried they were reversed again back to their original orientation.

When tested the glove of the invention was significantly easier to don by the damp hand.

Example 9

Example 5 was repeated omitting the hexadecylpyridinium chloride.

CLAIMS

1. A medical glove which may be donned by a dry or damp hand which comprises a microtextured medical glove the inside surface of which is provided with one or both of a surfactant and a silicone.

2. A glove as claimed in claim 1 in which the microtextured medical glove is a chlorinated medical glove.

3. A glove as claimed in either of claims 1 or 2 in which the inside surface of the glove is provided with a surfactant.

4. A glove as claimed in either of claims 1 or 2 in which the inside surface of the glove is provided with a mixture containing more than one surfactant.

5. A glove as claimed in either of claims 1 or 2 in which the inside surface of the glove is provided with a silicone.

6. A glove as claimed as claimed either of claims 1 or 2 in which the inside surface of the glove is provided with a surfactant and a silicone.

7. A glove as claimed in any of claims 1 to 4 or 6 in which the surfactant is cationic surfactant containing a salted nitrogen atom.

8. A glove as claimed in claim 7 in which the surfactant is hexyldecyl pyridinium chloride.

9. A glove as claimed in any of claims 1 to 4 or 6 in which the surfactant is an anionic surfactant containing an salted acid group.

10. A glove as claimed in claim 8 in which the surfactant in sodium lauryl sulphate.

11. A glove as claimed in claim 4 in which the mixture contains hexyldecyl pyridinium and sodium lauryl sulphate.

12. A glove as claimed in any of claims 1, 2, 5 or 6 in which the siloxane is polydimethyl siloxane.

13. A glove as claimed in claim 6 in which the silicone is polydimethyl siloxane and the surfactant is hexyldecyl pyridinium chloride.

14. A glove as claimed in any of claims 1 to 13 which has been microtextured by a means of moulding process.

15. A sterile glove as claimed in any of claims 1 to 14 within a bacteria proof pack.

16. A method of making a glove as claimed in any of claims 1 to 14 which comprises treating the inside surface of a microtextured glove with one or both of a surfactant and a silicone.

17. A method as claimed in claim 16 which comprises treating the glove with an aqueous solution of hexyldecyl pyridinium chloride and sodium lauryl sulphate.

INTERNATIONAL SEARCH REPORT

PCT/GB 92/00171

International Application No

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all)[6]

According to International Patent Classification (IPC) or to both National Classification and IPC

Int.Cl. 5 A61B19/04

II. FIELDS SEARCHED

Minimum Documentation Searched[7]

Classification System	Classification Symbols
Int.Cl. 5	A61B

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched[8]

III. DOCUMENTS CONSIDERED TO BE RELEVANT[9]

Category °	Citation of Document,[11] with indication, where appropriate, of the relevant passages[12]	Relevant to Claim No.[13]
X	WO,A,8 400 908 (LRC) 15 March 1984 see page 5 - page 6	1,3, 5-10, 12-16
X	WO,A,8 100 346 (AMERICAL HOSPITAL SUPPLY) 19 February 1981 see page 8, line 1 see page 6, line 1 - line 4	1-3,5,6, 12-16
X	EP,A,0 328 421 (COLUMBIA UNIVERSITY) 16 August 1989 see abstract	1,5,12, 15,16
A	US,A,4 329 312 (GANZ) 11 May 1982 see abstract	14
A	GB,A,1 343 411 (ETHICON) 10 January 1974 see claim 1	15

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° Special categories of cited documents :[10]

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

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IV. CERTIFICATION

Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report
02 APRIL 1992	21.04.92
International Searching Authority	**Signature of Authorized Officer**
EUROPEAN PATENT OFFICE	BARTON S.

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)

Category °	Citation of Document, with indication, where appropriate, of the relevant passages	Relevant to Claim No.
A	J NAT RUBB RES vol. 4, no. 1, pages 1 - 21; ROBERTS AND BRACKLEY: 'Surface treatment of rubber to reduce friction' cited in the application see the whole document	1
A	FR,A,2 240 700 (DOW CORNING) 14 March 1975	
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ANNEX TO THE INTERNATIONAL SEARCH REPORT ON INTERNATIONAL PATENT APPLICATION NO. GB 9200171 SA 55757

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on
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